UNITED STATES DISTRICT COURT NORTHERN DISTRICT OF ALABAMA NORTHWESTERN DIVISION

EDWIN R. BANKS,)
Plaintiff,)
v.) Case No.: 5:20-cv-0565-LCB
ALEX M. AZAR, II, in his official)
capacity as Secretary of the U.S.)
Dept. of Health and Human Services)
)
Defendant.)

<u>ORDER</u>

Before the Court are the parties' cross Motions for Summary Judgment. (Docs. 31 & 37). Plaintiff Edwin Banks ("Banks") filed this action for judicial review of the final decision of the Secretary of Health and Human Services in accordance with §§ 42 U.S.C. 405(g), 1395ff(b)(1)(A). Banks is appealing Administrative Law Judge Kelton's order denying his claims for Tumor Treating Field Therapy (TTFT) with dates of service in January, March, and April of 2018. (Doc. 31 at 20–21). Banks contends the Secretary is precluded from denying him coverage by virtue of collateral estoppel. *Id.* at 3. Banks relies upon the decision of Administrative Law Judge Gulin for this proposition. *Id.* at 17. For the foregoing

reasons, Banks's Motion for Summary Judgment is **DENIED** and the Secretary's Motion for Summary Judgment is **GRANTED**.

FACTUAL BACKGROUND

Banks is a retired Medicare beneficiary. (Doc. 31–1 at 22). In September of 2009, he was diagnosed with a type of brain cancer known as glioblastoma (GBM). *Id.* GBM tumors are usually highly aggressive with a survival period of approximately ten months after initial presentation. *Id.* Banks was "prescribed chemotherapy, radiation and surgery to treat his [GBM]." *Id.* Banks learned in September of 2013 that, despite treatment efforts, his cancer had progressed. *Id.* As a consequence of the cancer's progression, Banks was prescribed Optune in December of 2013. *Id.* Optune is a type of medical equipment that sends alternating electric fields – or tumor treating fields – into the brain. (Doc. 31–1 at 22). This treatment slows or stops cancer cell growth completely. *Id.* The Optune device requires frequent and substantial servicing which is billed as a monthly rental. *Id.* at 23.

PROCEDURAL BACKGROUND

On June 3, 2019, ALJ Bruce Kelton decided Banks's January, March, and April 2018 claims for TTFT were not medically reasonable and necessary. (Doc. 38–3 at 24). Therefore, their reimbursement was not permitted by Medicare. *Id.* On June 6, 2019, ALJ Jeffrey Gulin, however, issued an order that found that the Elec. Stim Cancer Treatment (also known as TTFT) was medically reasonable and necessary

and that Banks was entitled to coverage for the treatment during February 2018 and from May 2018 to January 2019. (Doc. 38–4 at 4–5). Banks appealed ALJ Kelton's determination to the Medicare Appeals Council. *Id.* at 29–35. The Council did not take up the appeal within 90 days allowing Banks to appeal the determination directly to this Court. (Doc. 38–3 at 2).

LEGAL STANDARD

In matters regarding disputed Medicare reimbursements, "[t]he findings of the [Secretary] as to any fact, if supported by substantial evidence, shall be conclusive." Vitreo Retinal Consultants of the Palm Beaches, P.A. v. U.S. Dep't of Health & Human Servs., 649 F. App'x 684, 689 (11th Cir. 2016) (quoting 42 U.S.C. §§ 405(g), 1395ff(b)(1)(A)). The Court's review is limited to "whether there is substantial evidence to support the findings of the Commissioner, and whether the correct legal standards were applied." Wilson v. Barnhart, 284 F.3d 1219, 1221 (11th Cir. 2002) (citing 42 U.S.C. § 405(g); Lamb v. Bowen, 847 F.2d 698, 701 (11th Cir. 1988); McRoberts v. Bowen, 841 F.2d 1077, 1080 (11th Cir. 1988)). "Substantial evidence 'must do more than create a suspicion of the existence of the fact to be established."" Wilson, 284 F.3d at 1221 (quoting McRoberts, 841 F.2d at 1080). Substantial evidence "is more than a scintilla, but less than a preponderance." Holland v. Comm'r of Soc. Sec., 530 F. App'x 860, 861 (11th Cir. 2013) (quoting Hale v. Bowen, 831 F.2d 1007, 1011 (11th Cir. 1987)).

DISCUSSION

I. Medicare Statutory Scheme

Title XVIII of the Social Security Act which is commonly referred to as the Medicare Act established a federal health insurance program "that provide[s] medical benefits to the elderly and disabled." Am. Acad. of Dermatology v. Dep't of Health & Human Servs., 118 F.3d 1495, 1496 (11th Cir. 1997). The Medicare program is administered by the Secretary of Health and Human Services (HHS). *Id*. This case involves Medicare Part B which is "a voluntary program that provides supplemental insurance to cover other health care costs." Id. at 1497. Under Medicare Part B, "beneficiaries receive medical treatment, and providers submit claims for government reimbursement." Vitreo Retinal Consultants of the Palm Beaches, P.A., 649 F. App'x at 690 (citing 42 U.S.C. § 1395n). The government reimburses "medical and other health services" only if those services are "reasonable and necessary." 42 U.S.C. §§ 1395k(a)(1), 1395y(a)(1)(A). To challenge a Medicare determination, the Medicare beneficiaries must first exhaust administrative remedies through the Medicare system's claim and appeal process. Cochran v. U.S. Health Care Fin. Admin., 291 F.3d 775, 779 (11th Cir. 2002).

A. Medicare Appeals Process

Regulations for Medicare Part B require, at the outset, a determination of whether an individual is entitled to benefits. 42 C.F.R. § 405.920. Parties aggrieved

by the "initial determination may request a redetermination by a contractor." 42 C.F.R. § 405.940. If the individual remains unsatisfied after the contractor's determination, he may seek a reconsideration from a Qualified Independent Contractor (QIC). 42 C.F.R. § 405.960. Within 60 days of notice of reconsideration, an individual has the right to a hearing before an ALJ if the individual files a written request for the hearing. 42 C.F.R. § 405.1002(a)(1).

Following an ALJ decision, the individual may request a review of the decision by the Medicare Appeals Council. 42 C.F.R. § 405.1048(a)(1). After the Secretary renders a final decision, the beneficiary can seek judicial review on the claim in a federal district court. *Cross Terrace Rehab Inc, LLC v. Sec'y, Dep't of Health & Hum. Servs.*, 797 F. App'x 503, 504 (11th Cir. 2020).

II. Collateral Estoppel¹

The sole issue before the Court is whether the HHS Secretary is collaterally estopped from denying Banks's coverage based on the prior decision by ALJ Gulin.² The doctrine of collateral estoppel, or issue preclusion, prohibits parties from

¹ The Secretary argues the Court should not consider any evidence not included in the record from ALJ Kelton's decision. However, "a court may take notice of another court's order only for the limited purpose of recognizing the 'judicial act' that the order represents or the subject matter of the litigation." *United States v. Jones*, 29 F.3d 1549, 1553 (11th Cir. 1994). The Court is looking to the fact that the ALJ Gulin's decision exists for the limited purpose of determining whether collateral estoppel applies in this case. Thus, the Court will take judicial notice of ALJ Gulin's decision.

² The parties dispute which decision was made final first. But the first step of the Court's analysis concerns whether collateral estoppel is applicable in Medicare appeals.

relitigating issues decided in a prior proceeding. *Sec. & Exch. Comm'n v. Rand*, 805 F. App'x 871, 875 (11th Cir. 2020) (citation omitted). Four elements are required to establish the appropriate application of collateral estoppel:

(1) the issue at stake must be identical to the one involved in the prior litigation; (2) the issue must have been actually litigated in the prior suit; (3) the determination of the issue in the prior litigation must have been a critical and necessary part of the judgment in that action; and (4) the party against whom the earlier decision is asserted must have had a full and fair opportunity to litigate the issue in the earlier proceeding.

Jordan v. Def. Fin. & Accounting Servs., 744 F. App'x 692, 694 (11th Cir. 2018) (citing CSX Transp., Inc. v. Bhd. of Maint. of Way Employees, 327 F.3d 1309, 1317 (11th Cir. 2003)).

The Supreme Court has long favored the application of collateral estoppel on final administrative decisions when the administrative body is "acting in a judicial capacity and resolves disputed issues of fact properly before it which the parties have had an adequate opportunity to litigate." *Astoria Fed. Sav. & Loan Ass'n v. Solimino*, 501 U.S. 104, 107 (1991) (citations omitted). In addition, "Congress is understood to legislate against a background of common-law adjudicatory principles." *Republic of Honduras v. Philip Morris Companies, Inc.*, 341 F.3d 1253, 1259 (11th Cir. 2003) (citing *Astoria*, 501 U.S. at 108). "Thus, where a common-law principle is well established . . . the courts may take it as given that Congress has legislated with an expectation that the principle will apply except 'when a statutory purpose to the contrary is evident." *Id.* (citing *Astoria*, 501 U.S. at 108). "In order to abrogate a

common-law principle, the statute must 'speak directly' to the question addressed by the common law." *United States v. Texas*, 507 U.S. 529, 534 (1993) (internal citations omitted).

The Secretary contends that collateral estoppel is inapplicable to the Medicare Appeals Process. (Doc. 37 at 14). The Secretary first argues that "applicable Medicare regulations provide that ALJ decisions do not bind the Secretary in future cases." *Id.* 16–17. Next, he argues that the application of collateral estoppel would interfere with the Secretary's deference and discretion to implement the Medicare statute. *Id.* at 20. Finally, the Secretary argues the Medicare Act's presentment and channeling requirements are incompatible with the doctrine of equitable estoppel. *Id.* at 24.

A. The Court may consider the Medicare Act's statutory purpose when determining collateral estoppel's applicability to ALJ decisions made in accordance with the Act.

In his Motion for Summary Judgment, Banks argues collateral estoppel applies to the determination that his TTFT treatment was medically reasonable and necessary because the *Astoria* presumption was established in this case. (Doc. 39 at 8). Banks contends that the presumption was established because the agency acted in a judicial capacity and all the elements of collateral estoppel were present. *Id.* However, the *Astoria* presumption is not as cut and dry as Banks alleges. The statutory language of the Medicare Act does not state whether collateral estoppel is

appropriate. The Secretary argues, on the other hand, that the Medicare statute and regulations clearly show the legislative intent to bar the application of collateral estoppel to ALJ decisions. (Doc. 37 at 15).

The issue presented, then, is whether the Court can consider the intent of the legislature when the Act's text does not "speak directly" to the viability of collateral estoppel for these claims. In Republic of Honduras v. Philip Morris Companies, Inc., this Circuit considered whether the RICO statute preempted the application of the long-established and familiar principle of the revenue rule when RICO did not speak directly to the applicability of the revenue rule. 341 F.3d 1253, 1259 (11th Cir. 2003). In that case, the Court looked for "any evidence of a statutory purpose in the RICO statute that would except actions brought under it from the strictures of the revenue rule." Id. Similar to Republic of Honduras, this case concerns a longestablished and familiar principle: collateral estoppel. See Astoria 501 U.S. at 108. And the Medicare Act does not directly address its applicability to ALJ decisions. Considering the Eleventh Circuit's analysis in Republic of Honduras, this Court will also look to the statutory purpose of the Medicare Act to determine the viability of collateral estoppel to ALJ decisions made in accordance with the Act.

B. The Medicare scheme is incompatible with the doctrine of collateral estoppel.

In his Motion for Summary Judgment, the Secretary alleges that the Medicare statute and regulations bar the application of collateral estoppel because the

regulations do not accord conclusive effect to ALJ decisions, and the Council's de novo review under the statute gives the Council the ability to make an independent determination. (Doc. 37 at 16–20). In the Medicare Act, Congress gave the Secretary under Part B the authority to make regulations and initial determinations on whether an individual is entitled to benefits, and if so, the amount of benefits. 42 U.S.C. § 1395ff(a)(1)(A)-(B). The Medicare statute and regulations also provide for several layers administrative review for coverage denials. *Cross Terrace Rehab Inc, LLC*, 797 F. App'x at 504 (citing 42 U.S.C. § 1395ff; 42 C.F.R. §§ 405.920, 405.040, 405.960, 405.1000). It is only after these layers of review are exhausted that a Secretary's decision is final, and judicial review by a federal district court is permitted. *Id.* (citing 42 U.S.C. § 405(g)).

The statutory scheme of the Medicare appeals process appears incompatible with the doctrine of collateral estoppel. Medicare regulations clearly lay out that some decisions can be precedential. For instance, Council-level decisions become precedential if the Chair of the Departmental Appeals Board designates the decision as such. *See* 42 C.F.R. § 401.109. The term "precedential effect" in the regulation itself means that the Council's:

- (1) Legal analysis and interpretation of a Medicare authority or provision is binding and must be followed in future determinations and appeals in which the same authority or provision applies and is still in effect; and
- (2) Factual findings are binding and must be applied to future determinations and appeals involving the same parties if the relevant

facts are the same and evidence is presented that the underlying factual circumstances have not changed since the issuance of the precedential final decision.

Id. Since, the regulations are explicit about the precedential effect that a decision by the Council would carry, the implication arises that other appellate levels are distinguished from these precedential decisions. This would mean that an ALJ decision would not have a binding effect on other ALJs.

The Secretary also argues that the ALJ Gulin's decision should not be given preclusive effect because the Medicare statute and regulations also provide that the Council reviews the ALJ's decision de novo. (Doc. 37 at 19). To bind the Council to a decision of an ALJ, the Council could not perform a de novo review that the statute and regulations require. While the Secretary has not cited this proposition from this Circuit, the Court has found that several sister circuits share the view that ALJ decisions are not binding upon other ALJs or the Board. See W. Texas LTC Partners, Inc. v. Dep't of Health & Human Servs., 843 F.3d 1043, 1046 (5th Cir. 2016) ("[P]rior ALJ decisions are not binding on the DAB or other ALJs.); Porzecanski v. Azar, 943 F.3d 472, 477 (D.C. Cir. 2019) ("Because the review generally binds only the parties unless specifically designated as precedential, a favorable determination in one proceeding does not ensure that future claims will be approved.").

Based on the statutory and regulatory scheme of the Medicare Act, it is clear

that application of collateral estoppel in Medicare matters runs counter to legislative

intent and ALJ decisions should not be given preclusive effect. Based on its own

reasoning and persuasive authority from sister circuits, the Court finds that ALJ

decisions are not binding on other ALJs. Because no Council decision has been made

in Banks's case regarding whether the TTFT was medically reasonable and

necessary, ALJ Kelton's decision is not barred by collateral estoppel.

CONCLUSION

Based on the foregoing reasons, Banks's Motion for Summary Judgment

(Doc. 31) is **DENIED**, and the Secretary's Cross-Motion for Summary Judgment

(Doc. 37) is **GRANTED.**

DONE and **ORDERED** this March 30, 2021.

LILES C. BURKE

UNITED STATES DISTRICT JUDGE

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